K010945

JUN 1 2 2001

Instromedix®
A Card Guard Company
Today's Telemedicine Solutions

6779 Mesa Ridge Road, Suite 200
San Diego, CA 92121-2909

main 858.450.1750
fax 858.450.9718

www.instromedix.com

"510(k) Summary"

As Required By Section 807.92(c)

Contact Person: **Alden Kay**

Date **March 23, 2001**

Trade Name: **HeartCard®**

Common Name: *Telephone Electrocardiograph Transmitter and Receiver*

Classification Name: Telephone Electrocardiograph Transmitter and Receiver (Per 21 CFR section 870.2920)

Predicate Device: **Heart Alert, Inc. Personal Heart Device (PHD) (k963904)**

Device Description **The HeartCard®is a cardiac event recorder capable of storing three 30-second events in solid state ECG Memory. The device is activated by a Customer who experiences transient symptoms. The device is placed on the chest or uses a two-wire lead set for post event recording. The device records 30 seconds of ECG, after the Customer pushes the RECORD button. Up to three segments of ECG may be stored and then transmitted later in the form of an FM-modulated acoustic tone, when the SEND button is depressed. The HeartCard® is configured in a credit-card sized case about ¼ " thick.**

Predicate Equivalence: The HeartCard® is equivalent to the predicate device [Personal Heart Device (PHD)] as that device is the Instromedix HeartCard® as sold and marketed by another company [Heart Alert, Inc.] as an Over-The-Counter device.

Safety and Effectiveness: The HeartCard® is considered safe and effective for use when used in accordance with the instructions provided in the Owners Manual which accompanies each device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 12 2001

Mr. Alden Kay
Instromedix
6779 Mesa Ridge Road, Suite 200
San Diego, CA 92121-2909

Re: K010945
Trade Name: HeartCard, Model 5258
Regulation Number: 870.2920
Regulatory Class: II (two)
Product Code: DXH
Dated: March 23, 2001
Received: March 29, 2001

Dear Mr. Kay:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

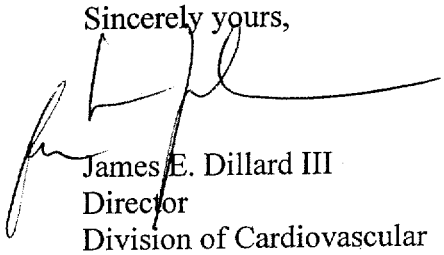
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might

have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,



James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): **K010945**

Device Name: **HeartCard**

Indications For Use:

You should consider using the HeartCard® and LifeWatch Heart Screening Service whenever you are concerned about your heart rhythm (i.e. during or after exercise) or if you experience the following symptoms that are suggestive of abnormal heart rhythms, and you would like to monitor these symptoms:

- Skipped Beats
- Pounding heart (Palpitations)
- Heart Racing or Irregular Pulse
- Lightheadedness or Faintness
- History of Arrhythmias

Contraindications for Use:

In order to use this service, you must be able to perform all of the following:

- Place the HeartCard on your chest and hold for at least 30 seconds.
- Operate a telephone.
- Operate a simple, push-button device.

Due to the possible seriousness of the abnormal heart rhythms that can be associated with these conditions, persons who have been diagnosed with the following conditions should consult their physician before using this service:

- Blockage of the arteries of the heart
- Heart valve problems
- Heart transplant
- Congestive heart failure
- Loss of consciousness

If you have any of these conditions, LifeWatch will need to obtain authorization from your physician within 35 days of your enrollment in the service.

Warning:

This device is not designed to be used with pacemakers or defibrillators. If you have either of these, you will not be allowed to enroll in the service.

This device also cannot predict or diagnose a heart attack or be used for chest pain monitoring.

510(k) Number (if known): **K010945**

Device Name: **HeartCard**

Need for Signed Physician Agreement:

Your agreement indicates you understand that LifeWatch (or affiliate) will contact your physician to verify in writing that you are their patient and that they are willing to be contacted in cases where there are clinically significant events involving your care.

Your agreement indicates you understand that if written verification is not received from your physician within 35 days of your enrollment, you will not be able to utilize any aspects of the LifeWatch (or affiliate) service until such verification is received by LifeWatch (or affiliate).

Your agreement certifies you understand that this service is not a substitute for physician care and that this is only a screening service.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K010945

Prescription Use____ OR Over-The-Counter Use X
(Per 21 CFR 801.109)

(Optional Format 1-2-96)